

## **STATUS OF CLAIMS**

Claims 1-18 are pending.

Claims 1-18 stand rejected by the Examiner.

## **REMARKS**

Reconsideration of the present Application is respectfully requested.

### **Claim Rejections Pursuant to 35 U.S.C. §102(b)**

Claims 1 and 9 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lewis et al. (U.S. Patent No. 6,392,327). Claims 10 and 18 have been rejected under 35 U.S.C. §102(a) as being anticipated by Jackson et al. (U.S. Patent No. 6,475,148). Applicant respectfully traverses these rejections for at least the following reasons.

35 U.S.C. §102 recites, in part:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Consistently, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See, M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).*

Applicant respectfully submits that the cited references do not teach each of the limitations of independent claims 1 or 10. Specifically, neither Lewis nor Jackson teaches at least a transdermal substance delivery device or method of transdermal substance delivery that includes at least one sensor for sensing reflected ultrasonic transmissions that are indicative of substance actually moved into tissue.

The present invention as claimed in independent Claim 1 uses at least one sensor *to sense reflected ultrasonic transmissions that are indicative of substance actually moved into tissue*. This is very different from the sensing elements as disclosed by Lewis. Lewis teaches that the sensing elements (20):

“generate an electrical output signal in response to the mechanical displacement from the drive elements 18. Any changes in the operational characteristics of the drive elements 18 which produces a change in the mechanical displacement or resultant sonic output (such as changes due to temperature variations, loading, stress, cracking or electrical inputs) are sensed by sense elements 20 which provide an electrical feedback output to sense signal circuit 30.”

*See Lewis at Col. 3, lines 13-22.*

Thus, the sensing elements 20 as taught by Lewis are used to sense changes in the operational characteristics of drive elements 18. In other words, the sensing elements of Lewis are designed and used for monitoring the equipment or mechanical components of the sonic transducer itself, which has nothing to do with the sensing of ultrasonic transmissions indicative of substance moving into tissue, as recited in Claim 1.

Similarly, the present invention as claimed in independent Claim 10 uses at least one sensor to sense reflected ultrasonic transmissions that are indicative of substance actually moved into tissue. The present Office Action asserts that Jackson discloses ultrasonic drug delivery via destruction of microspheres, and includes a sensor that senses substance movement from reflected

ultrasonic transmissions (current Office Action at page 2, last paragraph, ending on page 3).

Applicant strongly disagrees with this statement.

First, Applicant respectfully submits that the method of Claim 10, as originally written, is for ***transdermal*** substance delivery. The method as taught by Jackson is for destroying microspheres, such as microbubbles, microparticles and contrast agents (Jackson at Col. 2, line 1), that are ***introduced via intravenous injection or injection into the bloodstream or tissue***, with the circulatory system carrying the microspheres to the region targeted for treatment (Jackson at Col. 3, lines 52-58). It should be readily apparent that a ***transdermal*** push of a substance into tissue is not the same thing as ***an injection*** of microspheres into the body and the subsequent destruction of those microspheres to release the associated drug.

Additionally, Applicant submits that Jackson does not even disclose a sensor at all, no less a sensor for sensing reflected ultrasonic transmissions that are indicative of substance actually moved into tissue. The system of Jackson includes a transmit beamformer 12, a transmit beamform controller 14, a transducer 16, a receive beamformer 18, a scan converter 20, a display 22, a user interface 24, and an optional trigger device 26 (Jackson at Fig. 1 and at Col. 2, lines 22-28). It should not be surprising that such a sensor is absent in the system of Jackson, simply because, as explained above, Jackson does not teach a system of transdermal delivery into tissue. As stated herein, and also by the present Office Action, Jackson uses acoustic energy to destroy microspheres. If you are not pushing a substance into tissue transdermally, there is no need or benefit to have a sensor for sensing ultrasonic transmissions indicative of substance moved into tissue. To this effect, Applicant respectfully requests the Examiner to point specifically where Jackson discloses a sensor to sense reflected ultrasonic transmissions that are indicative of substance actually moved into tissue

(the present Office Action cites columns 2-4 generally), if the Examiner maintains the position that Jackson teaches such a sensor.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(a) and (b) rejections of claims 1 and 10, as both Lewis and Jackson fail to teach the invention recited in claims 1 and 10. Further, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(a) and (b) rejections of claims 9 and 18, as these claims ultimately depend from a patentably distinct independent base claim 1 or 10.

**Rejections based on 35 U.S.C. § 103(a)**

Claim 2 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, in view of Shimada et al. (U.S. Patent No. 5,267,985). Claims 3-8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, in view of Dellagatta (U.S. Patent No. 5,954,675). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson, in view of Shimada. Claims 12-17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson, in view of Dellagatta. Applicant respectfully traverses these rejections for at least the following reasons.

35 U.S.C. 103(a) sets forth in part:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For at least the reasons stated above, the cited references, either separately or in any combination, do not teach or suggest each of the limitations of claims 1 or 10. Specifically, as previously explained, neither Lewis nor Jackson teaches at least a transdermal substance delivery device or method of transdermal substance delivery that includes at least one sensor for sensing reflected ultrasonic transmissions that are indicative of substance actually moved into tissue. Similarly, neither Shimada nor Dellagatta teach at least a transdermal substance delivery device or method of transdermal substance delivery that includes at least one sensor for sensing reflected ultrasonic transmissions that are indicative of substance actually moved into tissue, as such a sensor is completely absent in the inventions of both Shimada and Dellagatta. Additionally, because of the complete absence of such a sensor, there is no suggestion or motivation to modify any single reference or to combine these reference teachings to meet such a limitation.

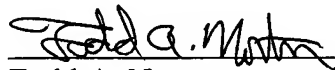
Accordingly, Applicant submits at least claims 1 and 10 are patentably distinguishable over the art of record. Applicant further submits that claims 2-9 and 11-18 are similarly distinguishable over the art of record, at least by virtue of their ultimate dependency from a patentably distinct base claim 1 or 10.

## **CONCLUSION**

Wherefore, Applicant believes that all outstanding grounds raised by the Examiner have been addressed and respectfully submits the present case is in condition for allowance, early notification of which is earnestly solicited. Should there be any questions or outstanding matters, the Examiner is cordially invited and requested to contact Applicant's undersigned attorney at his number listed below.

Respectfully submitted,

Date: May 3, 2006



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